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## PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53(b)(2).

Docket Number		PP/3640-2		Type a plus sign (+) inside this box -->		+
INVENTOR(S)/APPLICANT(S)						
LAST NAME	FIRST NAME	MIDDLE INITIAL	RESIDENCE (CITY AND EITHER STATE OR FOREIGN COUNTRY)			
Syrowicz	Diego		New York, New York			
TITLE OF THE INVENTION (280 characters max)						
METHOD AND APPARATUS FOR REMOVING AN UNDESIRE PRESENCE ON THE SKIN OF A USER						
CORRESPONDENCE ADDRESS						
Ostrolenk, Faber, Gerb & Soffen, LLP 1180 Avenue of the Americas New York, NY 10036 Customer Number 2352						
STATE	NY	ZIP CODE	10036	COUNTRY	U.S.A.	
ENCLOSED APPLICATION PARTS (check all that apply)						
<input checked="" type="checkbox"/>	Specification 19 Pages		<input type="checkbox"/>	Drawing(s) _____ Sheets		<input checked="" type="checkbox"/>
<input type="checkbox"/>	Other (specify)					
METHOD OF PAYMENT						
Our check No. _____ is enclosed to cover the Provisional Application filing fee.				PROVISIONAL APPLICATION FILING FEE AMOUNT (\$)		\$75
The Commissioner is hereby authorized to charge any additional or missing fee to Deposit Account Number: 15-0700						

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government:

☐

No.

☐

Yes, Agency and Government contract number are: \_\_\_\_\_

Respectfully submitted,

SIGNATURE



Date

02/16/00

TYPED NAME Steven S. Rubin

REGISTRATION NO. 43,063

☐

Additional Inventors are being named on separately numbered sheets and attached hereto.

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EXHIBIT A

Serial or Patent No.: \_\_\_\_\_ OFGS File No. PP/3640-2  
Filing or Issue Date: February 16 2000  
Applicant or Patentee: Diego Syrowicz  
For: Method and Apparatus for Removing an Undesired Presence on the Skin of a User

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS**  
**37 CFR 1.9(f) and 1.27(b) - INDEPENDENT INVENTOR**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under 35 USC §41(a) and (b) to the U.S. Patent and Trademark Office with regard to the invention entitled \_\_\_\_\_

described in

- ☒ U.S. Provisional Patent Application filed herewith  
☐ U.S. Patent Application Serial No. \_\_\_\_\_ filed \_\_\_\_\_  
☐ U.S. Patent No. \_\_\_\_\_ issued \_\_\_\_\_

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed or licensed or am under an obligation under contract or law to assign, grant, convey or license any rights in the invention is listed below:

- ☒ no such person, concern or organization  
☐ persons, concerns or organizations listed below\*

\*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities.  
37 CFR 1.27

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☒ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

NAME: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file in this patent application or patent, notification of any change of status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. 37 CFR 1.29(b).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 USC §1001, and that such willful false statements may jeopardize the validity of the patent application, any patent issuing thereon, or any patent to which this verified statement is directed.

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Name of Inventor

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***LFN Inc.***

*A venture by Group Five*

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## 1. Introduction to LFN's Business

LFN (Laser Follicle Neutralization) Inc. will build the most advanced permanent hair removal system in the market - *SmartLyte*™. The LFN system is an innovative way to use conventional laser hair removal systems to achieve a faster, safer, and cheaper method for people seeking a permanent solution to unwanted body hair. Using computer vision systems, artificial intelligence (AI), and robotics, LFN's systems automatically seek hair follicles in a high-speed fashion. For example, a woman using other laser or electrolysis methods could spend up to 12 often-painful hours removing the hair of her legs, and would spend up to three thousand dollars in the way. On the other hand, *SmartLyte*™ offers modern women who often neither have the time to lose, nor wish to spend too much money, a solution of three hours and \$300 to the same problem. LFN has the management, resources, and technology to become the premier hair-removal solution provider in the market.

*SmartLyte*™ will compete with other hair removal systems through a combination of pricing, quality, speed, safety, and convenience.

<i>Competitors' Methods</i>	<i>Disadvantages When Compared to SmartLyte™</i>
<i>Shaving</i>	<ul style="list-style-type: none"><li>• Non-Permanent</li><li>• Necessary at least once a week</li><li>• Time-Consuming</li></ul>
<i>Waxing</i>	<ul style="list-style-type: none"><li>• Non-Permanent</li><li>• Necessary at least once a month</li><li>• Time-Consuming</li><li>• Very Painful</li></ul>
<i>Chemical</i>	<ul style="list-style-type: none"><li>• Non-Permanent</li><li>• Necessary at least once a month</li><li>• Time-Consuming</li><li>• Somewhat Dangerous</li></ul>
<i>Electrolysis</i>	<ul style="list-style-type: none"><li>• Very Painful</li><li>• Extremely Time-Consuming</li></ul>
<i>Other Lasers</i>	<ul style="list-style-type: none"><li>• Very Costly</li><li>• Extremely Time-Consuming</li></ul>

## 2. Product

SmartLyte™ can detect multiple hair follicles simultaneously. Using computer vision technology, a robotic arm will scan the targeted regions of the body to identify individual hair follicles. The process of intelligent scanning substantially expedites the follicle neutralization procedure when compared to other available permanent hair removal technologies. The scanning module will be able to identify the exact location of every follicle and then neutralize it with the laser beam.

SmartLyte™ will have a “broad spectrum” laser that enables customization according to the area of the body being treated, the thickness and color of the hair, and the skin color. SmartLyte™ uses an Alexandrite laser, which is able to penetrate the hair follicle deeper than the customarily used ruby laser, thus allowing greater destruction of the follicle. The laser wavelengths penetrate deeply enough and with sufficient energy to be absorbed in the hair follicles, shafts, and bulbs. The absorption process generates a high enough temperature to destroy the hair structure and impair hair growth without damaging the delicate pores and structure of the skin.

Since SmartLyte™ is able to scan the skin and identify the exact location of each hair follicle, it does not endanger the pigmentation of the skin. As opposed to current similar devices, SmartLyte™ does not need to target a large area at a time; the laser beam need only be narrow enough to destroy one single follicle at a time. Although hundreds of follicles would have to be neutralized individually, the computer vision system will greatly expedite this process.

None of the current hair removal systems can claim permanent hair removal. Although some hairs may be permanently destroyed following existing laser therapy, most systems require multiple treatments to achieve permanent results. Successive treatments increase the number of hairs permanently destroyed and can also result in finer and lighter residual hairs. The SmartLyte™ system will permanently eliminate hair re-growth in one to two sessions.

LFN's product can be regulated to remove unwanted hair for a short period of time as well. This is particularly useful for some customers. For example, the product can be extended to other markets like male nose and ear hair removal, acne treatment, and tattoo removal.

### 3. Engineering and Product Development

The core competency of our business is to integrate laser and computer vision in a device that optimizes the speed and quality of hair removal.

There are currently six popular ways to remove hair: wax, shaving, creams, electrolysis, thermolysis, and laser. However, the first three procedures are non-permanent; electrolysis and thermolysis are both painful. Current advancements in laser technology provide customers with the best results, but the money and time that such a procedure entails dissuades many potential customers from abandoning the aforementioned traditional methods. Products in the market such as Epilight™, Epitouch™, Epilaser™, and LightSheer™ remove hair by projecting a laser onto whole sections of the skin, and taking a considerable amount of time to clear a small area. These technologies are patented and FDA-approved, ensuring that our product will not incur any health hazards.

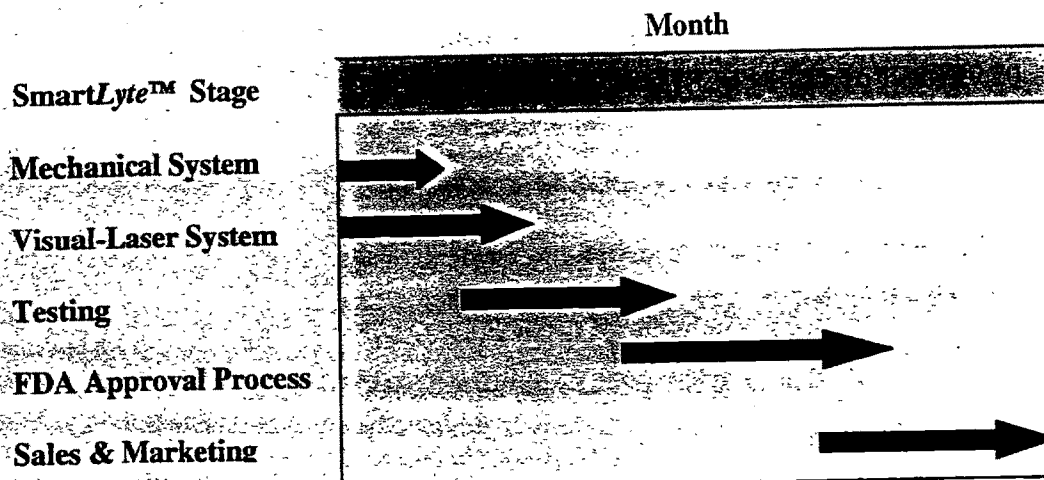
The *SmartLyte*'s Alexandrite laser selectively targets the melanin contained in hair follicles. By carefully matching pulse duration and energy input to the diameter of the desired target, the long pulse Alexandrite laser neutralizes the hair follicle and leaves the surrounding skin unaffected.

A significant portion of the R&D resources will be allocated towards the development of a sophisticated software package that implements the computer vision algorithms. As computer vision technology advances, our product must be upgraded accordingly. After the coding is complete, the *SmartLyte*™ technology will be rigorously tested with the Alexandrite laser and the robotic arm to ensure product reliability.

The R&D Division will be focused on refining current laser technologies and ensuring that the LFN has already spent a considerable amount of time researching the computer vision-based software and hardware. Once *SmartLyte*™ penetrates the mainstream market, the R&D Division will dedicate efforts towards making products more compact and versatile. R&D will work jointly with Marketing in order to understand and implement any changes in customer needs. Other services that we hope to provide in the future include vascular lesion removal and acne scar treatment.

Presently our Technical Director, Laser Guy from MIT, is supervising our research. He will continue in this capacity for at least the next five years. Having been the researcher involved with all our activities to this point, he is well qualified to continue our research efforts.

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#### 4. Financial Projections

Most of the people who will consider a permanent hair-removal solution like LFN are women from medium and highly urbanized areas, domestic and abroad. In the US, about 20% of the 120 Million women in such areas would consider LFN. Thus the US market alone is at least 25 Million women. The reason why a solution like LFN would be convenient is that the average woman spends around 30 hours and \$50 a year in hair removal in one way or another. At \$300, LFN would be a very attractive substitute.

We foresee that machine costs will be \$80,000 per machine in parts, labor, and distribution costs. Since in average such a machine would be able to service an average of 1,200 women a year (at 3 hours and \$300 a session), a machine would be able to pay for itself (and the cost of operation and location) in less than a year. The business of LFN promises to be very profitable, having an after-tax profit per machine of \$0.5 Million for the total life of the machine.

LFN Inc. will pursue a market penetration strategy in two stages: individual machine sales and leases, and own franchise operation. LFN will push for a 20:1 ratio of machine operated by independent operators to machines in LFN-operated franchises. After four years of operations, yearly sales will hit around \$50 Million (15% of which will be destined to servicing



and training). Because margins are high, a yearly net margin of \$7 Million is expected.

[See Projection of Sales, Costs, and Profits]

#### 4.1 Funding and Leverage Strategy

The initial funding for LFN will be provided by the partners of Group Five and their families. As projected in the cash flows (see attached statements), the start-up would quickly run out of cash if not funded by a venture capital partner in its first stage. In the first year LFN needs will be in excess of \$4 Million. The second stage of LFN (year 2) will proceed after positive market reaction has been observed. A strong marketing campaign will be implemented. In fact, for the first three years marketing and customer care will take first place in LFN expenditures. Capital needs for the second stage will be approximately \$20 Million. Such funds will be initially provided by the same or another venture partner. However, pending on market conditions, this will be the year that LFN goes public. LFN will need a strong capital inflow in order to grow and get the momentum it requires.

Projections indicate that LFN will have a third and last year of extra external funds required. We believe, however, that by this time LFN will have gained a more economic access to the debt markets. Thus, LFN will borrow at this stage. From the fourth year on LFN will be running positive balances. LFN will try to achieve and maintain a 40% leverage ratio (40% debt to market, or alternatively, a 60% Debt-to-Equity ratio).

The per-stage progression of LFN ownership follows:

	Stage 1	Stage 2	Stage 3	Stage 4 ...
Group Five	60%	30%	15%	15%
Venture Firms	40%	45%	28%	0% (Sold Stock)
Stockholders	0%	25%	57%	85%
Debt / Market	5%	5%	40%	40%

#### 5. Manufacturing Plan

## 5.1 Core Manufacturing Capabilities and Processes

Manufacturing methods will be simplified due to the small numbers of components that constitute our product. A physical plant will be established at our headquarters to perform the assembly of the components in a cell-type environment. Our main supplier of laser component parts will be *Candela Corporation* of Wayland, MA. In the event that they are not able to ship according to our specifications, our secondary supplier will be *Cynosure Incorporated*, located in Bedford, MA. These parts will be shipped to us by motor freight.

By breaking down the assembly process into four major components (laser, computer vision, software, and robotic arm) we can greatly reduce labor costs/time. We are outsourcing the manufacturing process of the laser machine to our primary supplier, Candela Corporation. The computer vision to be implemented with technology acquired from the Massachusetts Institute of Technology Artificial Intelligence Lab located in Cambridge, MA. The robotic arm/system will be assembled in-house. Components for this arm will be obtained from Allied Electronics (TX), Lynxmotion (IL), and McMaster-Carr, as they all meet our quality standards. Doing business with the three of them will give us better prices and will provide us with backup services in case the main supplier of a part is unable to deliver it. The production of the software will not require extraordinary additional investments in terms of physical space. Once the first working copy has been developed, additional copies will be produced as needed in one of the cells. The computers needed to run the software will be supplied by Advanced Cybertech Corporation, a company that specializes in custom-made computers used for laboratory applications. This equipment will be shipped to us via UPS. Initially, we do not intend to accumulate inventory, as we will be manufacturing each unit after an order is placed.

With this manufacturing system, our labor costs and therefore our production costs will be the lowest in the industry. To maintain our advantage we have established lines of communication with all of our potential component suppliers. Most importantly we have an ongoing relationship with several universities and are actively participating in various studies and experiments relating to production methods. Keeping the pace with newly developed technology should prove beneficial to the company, as we will always be able to offer the latest technology available.

These machines are also approved by the Food and Drug Administration. All products must meet specifications that ensure the consumer's safety in terms of health risks. We do not

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anticipate generating any toxic materials at this time through the manufacturing process of these products. However, we will be closely monitoring all production to determine if any hazardous conditions (such as the presence of radiation) are induced. We have contracted with an environmental engineering company to advise us on any possible problems as well as solutions including the use of radiation badges on the production floor.

We anticipate the following outlays for this capital equipment:

Laser Machine	\$60,000
Computer	\$7,000
Software copy	\$5,000
Robotic arm	\$10,000
Safety Devices	\$5,000

We envision a very simple cell/laboratory in our headquarters equipped with the basic research equipment we need. This will reduce the overall cost of the machine, as well as its weight and space needed to operate it. Since commercial space (square feet) is expensive, our customers will appreciate having to use less space to accommodate the new machine

## 5.2 Distribution/Shipping

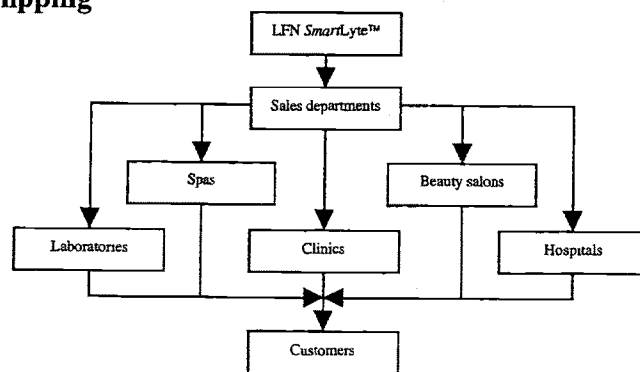


Figure 1 LFN's distribution channels

The distribution channels for the LFN technologies are as shown in Figure 1. More than 90% of the equipment/software packages will be delivered to spas and beauty salons through

wholesalers, with the remainder being delivered directly to hospitals, clinics, and dermatology labs; storage and delivery are covered by the federal regulations, which ensure practical standards for the supply and quality control of medical equipment.

LFN will have sales offices around the globe. To cater to the requirements of each of our clientele, our company will have sales offices with trained technicians operating in all major metropolitan areas. The sales requirements can be consolidated to our main branch in Cambridge, MA and be forwarded to the plants, or can be sent directly to the plants from the sales office. The pricing of the products is done based on the base pricing available from our headquarters and the cost of production. Produced goods are sent to the warehouse, or the customer, or the sales office. LFN will use an ORACLE database tailored to meet our individual needs in automating these procedures and various other related operations.

The system is comprised of modules for the following:

- Order processing
- Costing
- Inventory management
- Packaging
- Loading
- Shipping
- Billing
- Payment collection

The system runs in the all domestic and international offices of LFN.

Initially , LFN's product will be sold in health spas and beauty clinics in urban areas in the US which have viable market potential and a significant middle to upperclass population who would would be willing to finance treatments in clinics.

LFN plans to employ regional sales managers and engage independent brand representatives to solicit, supervise and otherwise market the product. The Company will employ one regional sales manager and plans to contract with several other independent sales

representatives at health clinics like SpaThira.

## **6 Sales and Marketing**

Women constitute more than half of the U.S. population. Appendix x summarizes the response of a survey conducted by our company. This data, along with market research conducted by competing firms, suggests that at least 20% of women (25 million) would consider permanent hair removal by the year 2002, provided procedures are safe, painless and cost-effective. At an average of \$400 spent per treatment, these 25 million women size the market at \$10 billion in the U.S. alone. Out of these 25 million women, at least 5 million would consider laser treatments over other alternatives, generating \$2 billion in revenues. Based on population growth estimates provided by the U.S. Census Bureau, this market is expected to grow at nearly 0.5% per year. If we consider international markets, particularly in industrialized and emerging markets, the expected number of women who would consider permanent hair removal treatment exceeds 100 million.

On average, LFN expects that each machine will generate over \$1,000,000.00 in revenues to each customer over a machine's lifetime (10 years). That means that LFN can expect to generate at least \$1 in sales for every \$10 generated by their customers. The market for laser hair removal machines is therefore over \$200 million.

### **6.1 Competitors**

From a purely competitive standpoint, LFN would be in an enviable position; our state-of-the-art artificial intelligence technology would provide the fastest and most cost-effective treatment in the market. One of the traditional inconveniences of laser treatments is its dependence on human beings to target each follicle. Besides being an arduous, labor-intensive job which requires highly skilled personnel, the procedure is prone to errors and requires multiple sessions for completion. Costs exceed well over \$1000.00 for treatment completion. LFN's procedure on the other hand, would cost only \$200 per 2-hour session, with an expected number of 2 sessions for treatment completion. Machine operators would only need a basic training on how to use the machine and how to monitor treatment progress, since our software will completely automate the scanning/laser targeting procedure. Table 2 compares LFN to the

present machine suppliers, and Table 3 shows the pricing estimates for PermaLase, an actual service provider that uses laser technology, compared to suggested prices to be offered by LFN. The market is still highly fragmented and relatively young because laser suppliers have only recently obtained FDA approval.

Company	PALOMAR MEDICAL TECHNOLOGIES EpiLaser	SHARPLAN EpiLaser SilkLaser	LFN SmartLYTE™
Type of Laser	Ruby	Ruby	Alexandrite
Availability	Purchase	Purchase	Purchase, Lease
Other uses	---	Tattoos Pigmented lesions	Future consideration for acne and wrinkles
Cost	\$120,000	\$129,000	\$125,000
Treatment Protocol	Shaving Use of Cooling Handpiece	Shaving Light Gel Coating Proprietary Grid Targeting System	Shaving Moisturizing Cream
Shortcomings	* Time required for cooling tissue * Possible hyperpigmentation and hypopigmentation * Not as effective on light or telogen hair * Labor intensive	* Possible hyperpigmentation and hypopigmentation * Not as effective on light or telogen hair * Not very effective on dark skin or moles * Labor intensive	* Training needed to operate (which will be provided as part of the purchase/lease)
Speed of treatment	Slower (7)	Fast (8.5)	Faster (10)
Likelihood for more than two treatments	Yes	Yes	No
Target of laser beam	Melanin	Melanin	Melanin

Table 2: Competitive analysis of SmartLYTE™ with respect to some of its competitors.

Service provider	PermaLase™	LFN SmartLYTE™
Upper lip	\$200	\$100
Chin	\$250-350	\$100
Eyebrow area	\$300	\$100
Both underarms	\$350	\$175
Nipples/Breasts	\$350	\$100
Bikini area	\$300-400	\$150
Both forearms	\$600	\$150
Back	< \$1500	\$250
Both lower legs	\$1200	\$200
Both thighs	< \$1400	\$200
Full facial beards	< \$900	\$300

Table 3: Price comparison for treatment of specific body parts.

### 6.1 Substitutes

Every year, about 1 million women in the United States use electrolysis. The pain and risks associated with the use of needles has limited the market penetration for such a technology. The development of no-needles electrolysis procedures has made this technology much more attractive although it still takes longer and many more sessions than lasers. Out of the needle-less electrolysis suppliers, Removatron owns 80% of the market. Perhaps the most threatening emerging substitute is a company called Permanex, which sells a Q-Tip style applicator that kills roots using the skin's biochemistry. The main weakness of this product is that its effectiveness depends on the skin's hydration and may be affected by the client's diet, hormone cycle, and allergic reactions. Because the system is targeted for residential use, customers end up investing over \$600.

## **6.2 Threat of new entrants**

LFN's expertise in artificial intelligence and computer vision will prevent direct competitors from copying our approach. In addition, the training provided to our customers will foster customer loyalty, establishing entry barriers to new companies trying to enter the market. Patenting LFN's technology and methods will prevent other firms from copying our products and ensure that LFN will remain at the technological forefront.

## **6.3 Marketing Plan**

### **6.3.1 Pricing Strategy**

Each machine will be priced at \$125,000. This allows businesses to charge \$100 per hour and have the machine pay for itself in one year, assuming 8 hours of daily operation, 5 days a week. This price is comparable to that of other machine vendors in this market.

### **6.3.2 Promotion**

LFN will advertise itself aggressively at beauty trade shows and at popular female publications such as Glamour, Vogue, and Cosmopolitan. In addition to its advertisements, LFN-operated stores will offer discounts and perks to loyal end customers who have recommended our services to friends and acquaintances.

## **6.4 Sales Plan**

### **6.4.1 Distribution and penetration**

LFN can sell its machine to dermatologists, beauty salons, spas, and hospitals. In addition to the hardware and software, the sales contract will include training, technical support, financing, and advertisement through the local media in coordination with LFN's nation-wide advertisement network for the first year. Because sessions require less time and less intervention of skilled personnel than other methods, more sessions can be scheduled in a single day with considerable operating savings for the service provider. Because no needles are involved, as in the case of electrolysis, there are no sterilization costs, another source of savings.

LFN would also operate machines for its own profit and as a way of generating demand. Because U.S. customers are willing to pay a premium for convenience, we will package beauty



salon services and dermatology with our hair removal system. Customers would only need to come to one place to fulfill all their beauty needs. LFN operated beauty centers will be located at major cities across the U.S. Malls, hospitals, hotels, and spa resorts are the prime target locations because of their convenience to customers. We will target those demographic areas with the highest number of working women, who would like to spend less of their leisure time shaving or waxing their skin.

#### 6.4.2 Sales force profile and deployment

Every employee at LFN will be expected to have a general understanding of our product, starting with the sales force at our regional offices, all the way up to the CEO. Our sales force will also be trained in basic machine repair and troubleshooting, since they must show our customers that LFN products are reliable, versatile, and easy to use. About half of our sales force will possess technical backgrounds; the remainder will come from the health and beauty professions. At least one of the representatives assigned for a particular deployment should have more than 2 years of sales experience. Product information will be available to sales and support representatives on the web, which they can view from their laptop computers. Technology specialists will also be supplied with tools to make last minute repairs and adjustments to the products that will be demonstrated. Sales representatives will be deployed in pairs, one representative being a medical/aesthetic specialist and the second being a technology specialist. A customer support hotline will also be established, with representatives trained in the same way as the field representatives.

## 7 Board of Directors

We have also secured the assistance and support of the following business and industry experts to guide us in the decision-making. In order to remain abreast in current dermatological advances, we have selected the Vice-President of the American Academy of Dermatology as one of the members of this board. In addition, we will have Dr. Harold Varmus, NIH Director, as one of our advisors.

The technologies incorporated into our product are currently evolving at a relatively rapid

pace. We will consult with two members experienced in the fields of lasers and computer vision. Dr. James G. Fujimoto from MIT is well known for his research in the area of medical lasers. Dr. Berthold Horn has been recognized as one of the top professionals in the computer vision technology. They will provide the necessary information that will allow us to succeed and revolutionize this market.

The success of this product is not just based on the technology. We think that, by making laser hair removal fashionable in society, an increasing number of people will want to undergo the procedure. Thus, we have selected Ms. Anna Wintor, the editor in chief of *Vogue*, as a publicity advisor. Ms. Wintor is well known for her leadership in promoting medical research through her popular magazine.

## 8 Risks, Liabilities and Regulations

New medical products have to get approval by the FDA through the Investigational Device Exemption (IDE), where a proposal is submitted and a process of trials takes place. This process usually takes a substantial amount of time, approximately two years or more.

For products that use components already tested and used in the health care industry, the process through which the FDA grants a license number is called the 510K. In this process, the trials are substituted by comparison to existing products. For this kind of process, the FDA has become more efficient in granting the licenses. The process takes anywhere from three months to a year, usually six months.

Since *SmartLyte*<sup>TM</sup>'s laser and robotic arm components that are already approved by the FDA, it will only be necessary for LFN to go through the 510K process, which should take no more than one year.

Along with our machines we must train the operators that will use the aforementioned equipment. We also have to include an operator's manual with reference to physicians that will be willing to address the personal concerns of the clients. Even though the machine will be FDA-approved, it is imperative that LFN has liability insurance. This can be done through any commercial broker such as *Signa*.

In case of injury caused by malfunction of the device, LFN shall keep an internal record of the failures and correct them internally. Only problems that persist will be reported to the

FDA through the complaints system according to their specifications.

## **9 Management Team**

### **Diego Syrowicz -- CEO and President, Sales and Marketing**

Mr. Syrowicz is a master's candidate in Electrical Engineering and Computer Science, holding a bachelor's degree in EECS and Management Science at the Massachusetts Institute of Technology. He is a founding partner of QuetzalNET, established in November 1995: the first internet consulting group of Guatemala, which provided the first and still largest Guatemalan information site on the Internet. Prior to his studies at MIT, he founded SYRSCO- a private meat distribution company targeted towards middle and high-income families in Guatemala City.

Mr. Syrowicz has extensive work experience in operations research and process engineering, including summer internships with Analog Devices, and research positions with the Management and Economics Research Center.

### **Hernan Mercado-Corujo -- Chief Technology Officer**

Mr. Mercado-Corujo is a bachelor's candidate in the Department of Mechanical Engineering who has been involved with the design and manufacture of semiconductor equipment with EATON Corporation in Beverly, MA. Mr. Mercado-Corujo has also been involved with the design of an experimental apparatus for a NASA's zero-gravity flight.

Mr. Mercado-Corujo will also be taking special training in the following months in the area of robotics.

### **Guillermo Oropeza -- Corporate Vice President, Sales and Marketing**

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Mr. Oropeza, a bachelor's student in Mechanical Engineering at the Massachusetts Institute of Technology, has been instrumental in the design and manufacture of consumer products, including a coffeemaker re-engineered for Kaurig intended for home users, as well as a virtual bike for MIT 's Design and Manufacturing senior design class.

**Ramon L Rodriguez -- Corporate Vice President, Research and Development**

Mr. Rodriguez is a master's student in Electrical Engineering at MIT, holding a bachelor's degree in E.E. from the same institution. He has held several leadership positions at MIT and has experience in Marketing and Product Development with Hewlett Packard, the Lawrence Livermore National Laboratory, and the MIT Research Laboratory of Electronics. He is a National Science Foundation Minority Graduate Fellow.

**Jonathan K Kisner --- Chief Financial Officer, Treasurer**

Mr. Kisner is a bachelor's student in Economics and Mechanical Engineering at the Massachusetts Institute of Technology. He has played an active part in the design and manufacture of plant machinery for petroleum refineries and has also worked as a technical consultant for Bateco S. A. Textile Company in the troubleshooting of factory machinery and efficiency control.

**Somak Chattopadhyay -- Chief Operations Officer**

Mr. Chattopadhyay, a bachelor's student in Mechanical Engineering at the Massachusetts Institute of Technology with a concentration in Management/Finance, has been involved in many ventures in design and manufacturing. Such ventures include an internship with Northwest Instruments Systems, Inc. in Richland, WA where he designed an interface, which is patent-pending, for a micro-chemical analyzer to assess pollutant concentration in water supplies using standardized techniques of photo-spectrometry.

